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EXAMINER	
SCHMIDT, EMILY LOUISE	
ART UNIT	PAPER NUMBER
3767	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/664,004	BURKETT ET AL.	
	Examiner	Art Unit	
	Emily Schmidt	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *4,5,8,9 and 18-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 6, 7, 10-17, 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1, 3, 6, 10, 11, 13, and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by van Sloun et al. (US 2004/0010189 A1).

With regard to claim 1, van Sloun et al. teach an intraluminal guide wire, comprising: an elongated wire core having a proximal core section and a distal core section having a tapered distal end (Fig. 1 tapering region indicated at 9); wherein at least a section of the elongated wire core includes at least one of randomized and non-randomized tactile surface contours (Fig. 1 provided by member 6); an uninterrupted polymer coating with a generally constant outside diameter adhering to and contiguous with the at least one of randomized and non- randomized tactile surface contours for at least a portion of the elongated wire core including at least a portion of the tapered distal end and having a surface contour that follows the at least one of randomized and non-randomized tactile surface contours in the elongated wire core (Fig. 1 coating 7); and a flexible tubular member disposed over the distal core section (Fig. 1 member 6).

With regard to claims 3, 6, 10, and 11, see contours provided by 6.

With regard to claim 13, see flexible member 6 and coating 7.

With regard to claim 15, the coating is Teflon ([0021]).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 2 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over van Sloun et al. (US 2004/0010189 A1) as applied to claim 1 above, and further in view of McMahon (U.S. Patent 6,296,616).

With regard to claim 2, van Sloun et al. teach an intraluminal guide wire substantially as claimed. Van Sloun et al. do not teach the size of member 6. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of van Sloun et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claim 7, van Sloun et al. teach an intraluminal guide wire substantially as claimed. Van Sloun et al. do not disclose the size of member 6. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to vary the number of contours and thus the spacing of the contours to place it within a range of .05 cm to 2 cm because it would serve as a means to adjust the surface contact area and thus the friction to achieve a desired amount of frictional resistance. Further, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). The peaks of the contact regions have a spacing of .005 cm to .5 cm (Col. 2 lines 57-58) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of van Sloun et al., with a spacing of about .05 to 2 cm as McMahon discloses an overlapping range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

5. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over van Sloun et al. (US 2004/0010189 A1) as applied to claim 1 above, and further in view of Murayama et al. (US 2004/0039309 A1).

With regard to claim 14, van Sloun et al. teach a guide wire substantially as claimed. Van Sloun et al. do not disclose the material of the guide wire. However, Murayama et al. teaches a guide wire with two different sections (Fig. 7 sections 2 and 3). The two sections are

made from different alloys (Pg. 4 [0070]), the distal section (Fig. 7 section 2) is made from a Nickel-Titanium alloy (Pg. 4 [0073]) and the proximal section (Fig. 7 section 3) is made from a stainless steel (Pg. 4 [0071]). This provides the catheter with a high pushability and a high torque transmission which enhances operationality and improves trackability ([0070]). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make the guide wire in van Slounet al. out of steel and a nickel-titanium alloy because Murayama et al. teach this to enhance guide wire performance.

6. Claims 1-3, 6, 7, 10, 11, and 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltze et al. (US6,033,720) in view of McMahon (U.S. Patent 6,296,616), Tezuka (US 6,251,085 B1), and Sepetka (US 5,228,453).

With regard to claim 1, Stoltze et al. teach an intraluminal guide wire, comprising: an elongated wire core having a proximal core section and a distal core section having a tapered distal end (Fig. 3 core 10a); and an uninterrupted polymer coating with a generally constant outside diameter adhering to and contiguous with the surface for at least a portion of the elongated wire core including at least a portion of the tapered distal end and having a surface contour that follows the surface in the elongated wire core (Fig. 3 coating 17). Stoltze et al. does not teach the wire core to have tactile surface contours or that the coating follows such contours. However, McMahon teaches a guide wire with a coating with a generally constant outer diameter with tactile surface contours which function to reduce surface contact and resistance to the movement of the guide wire (Fig. 1, Col. 3 lines 1-4). Tezuka teaches creating surface contours in a guide wire coating by allowing the coating to follow the surface contours of the wire underneath (Fig. 1, Col. 2 lines 50-57, and Col. 2 line 63- Col. 3 line 5) this also reduces surface

contact for ease of movement. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide surface contours in the coating of Stoltze et al. as in McMahon by following surface contours in the core of the guide wire as in Tezuka because they teach that such contours are beneficial for reducing surface contact of the guide wire and reducing resistance to movement. Stoltze et al. does not teach a flexible tubular member disposed over the distal core section. However, Sepetka teaches using a flexible coil to increase radiopacity and improve torque (abstract, Col. 3 lines 27-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a flexible tubular coil about the distal end of Stoltze et al. because Sepetka teaches that such to increases radiopacity and improves torque.

With regard to claim 2, Stolze et al. does not teach surface contours to have a surface to peak amplitude in a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Stolze et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With regard to claims 3, 6, 7, 10, and 11, see contours in McMahon and Tezuka.

With regard to claim 14, the proximal section is formed of stainless steel and the distal portion is formed of a titanium nickel alloy (Col. 3 lines 66-67, Col. 4 lines 14-18).

With regard to claim 15, see Col. 4 lines 56-57.

With regard to claim 16, Stolze et al. teach an intraluminal guide wire, comprising: an elongated core having a proximal core section and a distal core section including a taper transitioning to a distal end (Fig. 3 core 10a); and a polymer coating of generally non-uniform thickness adhering without a gap to at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core (Fig. 3 see coating 17). Stoltze et al. does not teach the wire core to have tactile surface contours or that the coating follows such contours. However, McMahon teaches a guide wire with a coating with a generally constant outer diameter with tactile surface contours which function to reduce surface contact and resistance to the movement of the guide wire (Fig. 1, Col. 3 lines 1-4). Tezuka teaches creating surface contours in a guide wire coating by allowing the coating to follow the surface contours of the wire underneath (Fig. 1, Col. 2 lines 50-57, and Col. 2 line 63- Col. 3 line 5) this also reduces surface contact for ease of movement. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide surface contours in the coating of Stoltze et al. as in McMahon by following surface contours in the core of the guide wire as in Tezuka because they teach that such contours are beneficial for reducing surface contact of the guide wire and reducing resistance to movement. Stoltze et al. does not teach a flexible tubular member disposed over the distal core section. However, Sepetka teaches using a flexible coil to increase radiopacity and improve torque (abstract, Col. 3

lines 27-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use a flexible tubular coil about the distal end of Stoltze et al. because Sepetka teaches that such to increases radiopacity and improves torque.

With regard to claim 17, see contours in McMahon and Tezuka.

7. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltze et al. (US6,033,720), McMahon (U.S. Patent 6,296,616), Tezuka (US 6,251,085 B1), and Sepetka (US 5,228,453) as applied to claim 1 above, and further in view of Slaikeu et al. (US 5,443,907).

With regard to claims 12 and 13, Stolze et al. and Sepetka teach a guide wire substantially as claimed. Stolze et al. and Sepetka do not teach the coating to be disposed under or over the flexible member. However, Slaikeu et al. teach a flexible member which is encased in a polymer coating the coating provides a low friction coating (Col. 5 lines 29-35, Col. 7 lines 1-4) while the flexible member provides radiopacity (Col. 8 lines 46-61). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to surround the flexible member with the polymeric coating in Stoltze et al. and Sepetka as in Slaikeu et al. because this allows for the guide wire to be viewed with fluoroscopy while maintaining low friction for ease of maneuverability.

8. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoltze et al. (US6,033,720) in view of McMahon (U.S. Patent 6,296,616), Tezuka (US 6,251,085 B1), Sepetka (US 5,228,453), and Slaikeu et al. (US 5,443,907).

With regard to claim 31, Stoltze et al. teach an intraluminal guide wire, comprising: an elongated wire core having a proximal wire core section and a distal wire core section including a taper transitioning to a distal end (Fig. 3 core 10a); a polymer coating of generally non-uniform thickness adhering to and contiguous with at least a portion of the distal core section including at least a portion of the tapered transition with a coating profile not following a tapered profile of the elongated core (Fig. 3 coating 17), the proximal core section includes a high strength steel and the distal core section includes a nickel-titanium alloy (Col. 3 lines 66-67, Col. 4 lines 14-18); and the polymer coating includes a fluoropolymer (Col. 4 lines 56-57).

Stoltze et al. does not teach the wire core to have tactile surface contours or that the coating follows such contours. However, McMahon teaches a guide wire with a coating with a generally constant outer diameter with tactile surface contours which function to reduce surface contact and resistance to the movement of the guide wire (Fig. 1, Col. 3 lines 1-4). Tezuka teaches creating surface contours in a guide wire coating by allowing the coating to follow the surface contours of the wire underneath (Fig. 1, Col. 2 lines 50-57, and Col. 2 line 63- Col. 3 line 5) this also reduces surface contact for ease of movement. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide surface contours in the coating of Stoltze et al. as in McMahon by following surface contours in the core of the guide wire as in Tezuka because they teach that such contours are beneficial for reducing surface contact of the guide wire and reducing resistance to movement. Stoltze et al. does not teach a flexible tubular member disposed over the distal core section. However, Sepetka teaches using a flexible coil to increase radiopacity and improve torque (abstract, Col. 3 lines 27-28). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to

use a flexible tubular coil about the distal end of Stoltze et al. because Sepetka teaches that such to increases radiopacity and improves torque.

Stolze et al. does not teach surface contours to have a surface to peak amplitude in a range of about .0002 to .002 inches. However, McMahon teaches a guide wire with a plurality of contact and non-contact regions (Fig. 1 guide wire 10). These peaks have a height of about.01-.1mm which is approximately .0003 - .003in. (Col. 2 lines 59-61) and are used to reduce resistance (Col. 3 lines 1-14). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to create surface contours, in the guide wire of Stolze et al., with a surface-to-peak amplitude of about .0002 to .002 inches as McMahon substantially discloses such a range to reduce the surface contact between the guide wire and the lumen through which it passes and is effective in reducing resistance. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Stolze et al. and Sepetka do not teach the coating to be disposed under the flexible member. However, Slaikeu et al. teach a flexible member which is encased in a polymer coating the coating provides a low friction coating (Col. 5 lines 29-35, Col. 7 lines 1-4) while the flexible member provides radiopacity (Col. 8 lines 46-61). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to surround the flexible member with the polymeric coating in Stoltze et al. and Sepetka as in Slaikeu et al. because this allows for the guide wire to be viewed with fluoroscopy while maintaining low friction for ease of maneuverability.

Response to Amendment

9. The amendments to the drawings have been entered and are sufficient to overcome the drawing objections.

Response to Arguments

10. Applicant's arguments filed February 22, 2010 have been fully considered but they are not persuasive. Regarding Applicant's arguments with respect to van Sloun, Applicant has argued that because the coating is on the coils it is not adhering to and contiguous with the core. The Examiner maintains that the surface contours can be formed by member 6 and be considered to be on the core. The contours are included with the core via member 6. Regarding Applicant's arguments with respect to Stolze and McMahon, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Though Stolze may have a coating it does not negate further benefit as could be added by McMahon as rejected.

Conclusion

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Schmidt whose telephone number is (571) 270-3648. The examiner can normally be reached on Monday through Thursday 7:30 AM to 5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Emily Schmidt/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767